

6-29-04

IFW

PTO/SB/21 (02-04)

Approved for use through 07/31/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

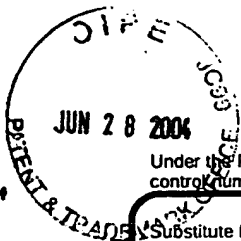
TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/813384	
	Filing Date	MARCH 30, 2004	
	First Named Inventor	DELOACH, REUBEN E.	
	Art Unit		
	Examiner Name		
Total Number of Pages in This Submission	4	Attorney Docket Number	

ENCLOSURES (Check all that apply)		
<input checked="" type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance communication to Group
<input checked="" type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
<input type="checkbox"/> Amendment/Reply	<input type="checkbox"/> Petition	<input type="checkbox"/> Appeal Communication to Group (Appeal Notice, Brief, Reply Brief)
<input type="checkbox"/> After Final	<input type="checkbox"/> Petition to Convert to a Provisional Application	<input type="checkbox"/> Proprietary Information
<input type="checkbox"/> Affidavits/declaration(s)	<input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address	<input type="checkbox"/> Status Letter
<input type="checkbox"/> Extension of Time Request	<input type="checkbox"/> Terminal Disclaimer	<input type="checkbox"/> Other Enclosure(s) (please identify below):
<input type="checkbox"/> Express Abandonment Request	<input type="checkbox"/> Request for Refund	
<input checked="" type="checkbox"/> Information Disclosure Statement	<input type="checkbox"/> CD, Number of CD(s) _____	
<input type="checkbox"/> Certified Copy of Priority Document(s)	Remarks	
<input type="checkbox"/> Response to Missing Parts/Incomplete Application	INFORMATION DISCLOSURE STATEMENT 3 PAGE	
<input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	CERTIFICATE OF MAILING 1 PAGE	
	BANK CHECK \$180.00	
	PTO/SB/08 A & B 2 PAGES	
SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT		
Firm or Individual name	REUBEN E. DELOACH	
Signature	R. E. DeLoach	
Date	JUNE 28, 2004	

CERTIFICATE OF TRANSMISSION/MAILING		
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.		
Typed or printed name		
Signature		Date

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.



PTO/SB/088 (10-01)

Approved for use through 10/31/2002. OMB 0651-0031

U.S. Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO		Complete if Known			
		Application Number	10/813384		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)		Filing Date	MARCH 30, 2004		
		First Named Inventor	DELOACH, REUBEN E.		
		Group Art Unit			
		Examiner Name			
Sheet	2	of	2	Attorney Docket Number	

OTHER PRIOR ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		MERCK INDEX, EIGHTH EDITION, P. 640, MALEIC HYDRAZIDE	
		SCIENCE 109, 588, 1949, MALEIC HYDRAZIDE	
		IPRONIAZID AS ANTIDEPRESSANT	
		CUTTING'S HANDBOOK OF PHARM. SIXTH ED. P. 628-629	
		ISONIAZID AS TUBERCULOSIS DRUG	
		CUTTING'S HANDBOOK OF PHARM. SIXTH ED., P. 39-40	
		ISAYIN-YHIO-SEMICARBAZONE AS ANTIVIRAL	
		CUTTING'S HANDBOOK OF PHARM. SIXTH ED. P. 125	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet 1 of 2

Complete if Known

Application Number	10/813384
Filing Date	MARCH 30, 2004
First Named Inventor	DELOACH, REUBEN E.
Art Unit	
Examiner Name	
Attorney Docket Number	

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

[illegible]

**Examiner
Signature**

Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, Washington, DC 20231. **DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO:** Assistant Commissioner for Patents, Washington, DC 20231.



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
Alexander, Va. 22313-1450

June 28, 2004

Information Disclosure Statement

Application Number: 10 / 813384
Filing Date: March 30, 2004
Inventor's Name: Reuben E. DeLoach
Title of Invention: "Hydrazide substrate safely shuts down disease activated protease to halt viral replication, cancerous cell division, and toxic protein generation"

1. This document is provided to comply with 37 C.F.R. § 1.56, or to disclose all information the applicant believes may be relevant to a determination of patentability for the disclosed invention. This invention pertains to applicant's discovery that shows hydrazides (R'NHNHCOR") are powerful protease inhibitors. Hydrazide molecules serve as enzyme substrates that simulates the peptide bonds (R'NHCOR") in proteins that are intrinsically targeted by protease enzyme cleavage action. However enzyme cleavage of the hydrazide substrate releases active hydrazine that immediately bond irreversibly with the protease enzyme causing its dysfunctional shutdown. That shutdown of protease action stops the production of all protein products by the cell which includes bioactive peptides necessary to induce cancerous cell division and growth, and also prevents protein products as viral coat protein that is required for viral replication.

2. Such hydrazide substrate medications have the ability to save millions of lives yearly by stopping cancer growth and metastasis and also by shutting down any viral infection including smallpox, SARS, HIV, and such like. Such diseases are threats to our families, ourselves, our nation, and our national security. Advancements in medical research would suggest that such hydrazide medications would have been discovered in the 1960 when this applicant first studied prior art examples that indicated a tremendous medical potential existed for such drugs once the biological mechanism was determined. However if others had made such discovery and has kept such information secret that prevents the millions afflicted from the benefits of a cure, then such would be tantamount to murder on a genocide scale and damaging to our true national security. Such depravity would be little different from the 9-11 attack that killed about 3000 people except that millions would be doomed to die each and every year for as long as such secrecy remains. However this applicant cannot evidence his suspicions except to say that research of the prior art items of 1953 and before by drug companies or academia would have easily revealed these medical discoveries. These items are listed in Cutting's Handbook of Pharmacology that the applicant purchased in 1974. The four prior art examples are explained in light of an understanding based on applicants discovery of the biological mechanism of hydrazides as follows:

3. Schoene and Hoffman, Science, 109, 588, 1949. discovered that **maleic hydrazide** spray stopped suckering growth, or the new growth of tobacco plants without harming the plants which is used in farming. The mechanism is somewhat explained in paragraph 1 above but simply stated the plant cell protease targets the hydrazide substrate with proteolytic cleavage action to release reactive hydrazine that results in protease enzyme shutdown. Such protease shutdown does not harm the plants or kill the cell but prevents protein products as peptides or new enzymes from forming that induce cell changes such as cell division and growth. As a result the production of bioactive

peptides that control cell division and plant growth is prevented by hydrazides or some precursors. This applicant's patent action does not state a claim that poses a conflict with this prior art example, but provides such to illustrate that the hydrazide biological mechanism that halts plant cell division and growth also has similar medical use to halt cancerous cell division and metastasis for mammalian cancer when lipid soluble hydrazides are used. (*Merck Index p.640, comment states, "Has the ability to inhibit the growth of plants without killing them," under maleic hydrazide, Eighth Edition*)

4. Fox in 1952 discovered that isoniazid provided anti-tuberculosis action. The mechanism of action for hydrazide is again evidenced by the fact that isoniazid supplies a hydrazide substrate that causes the dysfunctional shutdown of protease enzymes. Such protease shutdown prevents protein products as peptides and enzymes from forming that trigger cell division and growth much like the above example provides using maleic hydrazide. However because isoniazid does not have a substituent attached to the hydrazine terminal as needed to negate the toxic hydrazine effect of isoniazid and which is also needed to increase lipid solubility, the isoniazid product is toxic and largely unable to penetrate the cell area where protease can target it. The present invention remedies such short comings by alkylation of the hydrazine thus eliminating the toxic hydrazine effect, and which also increases lipid solubility and targeting providing an estimated 50 to 100 fold increase in action as a protease inhibitor of tuberculosis reproduction and growth. This invention does not claim that hydrazides kill tuberculosis as Fox was pursuing, but claims an increased efficacy and safety using the claimed hydrazide configurations as a means to halt reproduction or spread of any microorganism infection as stated by the claims. (*general comments regarding isoniazid p. 39-40, Cutting's Handbook of Pharmacology the Sixth Edition*)

5. Zeller in 1952, reportedly used iproniazid to provide antidepressive effects and concluded that iproniazid was a mono amine oxidase enzyme inhibitor (MAOI) which accounted for the antidepressant effects of this hydrazide drug. This long existing explanation as a MAOI is misleading. A more accurate explanation based on the hydrazide mechanism discovery shows that the cell protease is shutdown by iproniazid which in turn prevents the formation of cell protein products as the oxidase enzyme is only one example. However it is the oxidase enzyme system which destroys biogenic amine stimulants that provides the mental depressive state being remedied by iproniazid. And the shutdown of protease by iproniazid prevents production of oxidase enzymes which in the absence of such oxidase enzyme the biogenic stimulants increase to end mental depression. As such iproniazid only shuts down protease which indirectly prevents oxidase enzymes from being produced. This example shows how hydrazide type protease inhibitors will prevent protein products from forming which in this medical use example includes oxidase enzymes to provide antidepressant effects. The 50 year history of hydrazides antidepressant use illustrates the safety of the iproniazid drug as a protease inhibitor which also provides use to terminate cancer and viral infections as disclosed by this present invention. (*general comments p.628-629, Cutting's Handbook of Pharmacology the Sixth Edition*)

6. Thompson in 1953, reportedly discovered that isatin-thio-semicarbazone derivatives had the effect to stop smallpox and polio virus replication. This prior art discovery also evidences that the semicarbazone molecule supplies a hydrazide substrate invoking the mechanism that shuts down protease to halt viral coat protein and hence viral replication. In this case the hydrazide substrate is supplied by a complex semicarbazone molecule which obstructs targeting of the hydrazide by protease enzyme cleavage. Had Thompson discovered the mechanism used then his hydrazide design would not have used the isatin-thio-semicarbazone structure, but would have been optimized to benefit from protease targeting and lipid solubility. The basic shortcoming of Thompson's

invention belies the complex semicarbazone structure which unfortunately was obstructive to protease cleavage targeting and also had very little ability to penetrate the cell cleavage site area where it could be targeted by protease action. The current invention overcomes the limitations of Thompson's discovery with a molecule more representative of a protein fragment substrates that is more lipid soluble and that easily penetrates the cell proteolysis site where it is quickly targeted by protease cleavage action. As such the present invention solves a long-felt, long existing, unsolved need which optimizes efficacy and scope to provide a reliable means to rapidly eradicate any and all types of viral infections. (*see isatin-thio-semicarbazone p. 125, Cutting's Handbook of Pharmacology, Sixth Edition*)

Personal Disclosure Statement

7. The applicant has avoided revealing information disclosing his discoveries except to federal authorities on two occasion, and has otherwise responded to inquires by suppliers as Aldrich Chemical only to state that such work pertained to MAOI studies or was enzyme research related. The applicant became interested in undertaking such research when he owned and operated a research, engineering, and prototype development business and worked at the NASA facility in New Orleans. During unrelated work while searching for the properties of a chemical an unrelated entry in the Merck Index for maleic hydrazide took his attention. The entry stated that maleic hydrazide had properties that would stop the growth of plants without harming them. The applicant's curiosity moved him to undertake private research to determine the mechanism responsible believing that such may be applicable for human use to stop cancer cell division and growth.

8. The applicant's research was interrupted by severe family tragedies and personal losses. Foreign employment further prevented a return to research efforts except on a few brief occasions. Then in the mid 90's the applicant was inoculated with a virus following an emergency room visit with an eye injury where over a period of several years such progressed to a state symptomatic of AIDS, Kaposi's sarcoma, and viral conjunctivitis. At such time applicant discovered that the HIV virus was very sensitive to hydrazides and began experimenting to explore this and additional ideas for remedial treatment schemes for HIV/AIDS victims. This renewed pursuit evolved into this present patent application and two non-hydrazide discoveries which are yet to be filed with the PTO. Thanks for your understanding.

Respectfully submitted,



Reuben E. DeLoach
Applicant, pro se
3916 Linkmeadow Drive
Fort Worth, Texas 76008
(817)-560-2827

Enclosures:

PTO / SB / 08, A & B Information Disclosure forms
PTO / SB / 21 Transmittal form
Check for \$180, fee code 126, Submission of Information Disclosure Statement
Certificate of Mailing & post card receipt

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Commissioner of Patents
Alexander, Va. 22313-1450

Certificate of Mailing

Application Number: 10 / 813384
Filing Date: March 30, 2004
Inventor's Name: Reuben E. DeLoach
Title of Invention: "Hydrazide substrate safely shuts down disease activated protease to
halt viral replication, cancerous cell division, and toxic protein generation"

The applicant hereby certifies that the attached document or correspondence entitled:


Information Disclosure Statement

will be deposited with the United States Postal Service as first class mail Mail, with proper postage
affixed, and is addressed to the "Commissioner of Patents, Alexander, Va. 22313-1450, on this date:

June 28, 2004.

(ED001490257US)

Respectfully Submitted,



Reuben E. DeLoach
pro se applicant